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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,953	09/10/2003	Alexander Karl Huwig	20959/21409 (P63469)	3518
96448	7590	03/28/2011	EXAMINER	
Ivoclar Vivadent Inc. 175 Pineview Drive Amherst, NY 14228			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1613	
			NOTIFICATION DATE	DELIVERY MODE
			03/28/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/658,953	Applicant(s) HUWIG ET AL.	
	Examiner BLESSING FUBARA	Art Unit 1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-8,11-15,17-27,33 and 35-46 is/are pending in the application.
- 4a) Of the above claim(s) 6-8,13 and 21-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,11,12,14,15,17-20,27,33 and 35-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>011/12/2001</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The examiner acknowledges receipt of IDS, amendment and remarks filed 1/12/2010. Claims 1, 6-8 and 33 are amended. Ne claims 44-46 are added. Thus, claims 1, 2, 6-8, 11-15, 17-27, 33, 35-46 are pending. Claims 6-10, 13 and 21-26 are withdrawn from consideration; Claims 1, 2, 11, 12, 14, 15, 17-20, 27, 33 and 35-46 are under examination.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 2, 11, 12, 14, 15, 17-20, 27, 33 and 35-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes et al. (US 6,004,538) in view of Asano et al. (US 4,568,540).

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5. New claims 44-46 are of the same scope as claim 1. The phosphonate having $n=1, 2, 3$ or 4 are all variations of the phosphonic acid having the same backbone except there is evidence that the phosphonic acid having $n=1$ or 3 is unexpectedly superior over one having $n=2$ or 4. The rejection is modified with minor editorial correction of 1.5-3 to 2-3 and including new claims 44-46 in the rejection.

6. Hughes discloses liquid dentifrice and mouthwash compositions that comprise one or more of oral composition components that are selected from abrasives, binders such as xanthan gum and carboxymethylcellulose at 0.1-5%, humectants, surfactants, fluoride ion sources, anticalculus agents and sweeteners and additionally comprises dimethicone copolyol selected from alkyl- and alkoxy-dimethicone copolyols (abstract; column 5, lines 30-35, 52-65); may also include lipophilic flavorants and lipophilic antimicrobial compounds (column 4, lines 29-62). Silica gels or xerogels (column 6, line 10) or calcium carbonate (column 6, lines 22 and 23) are abrasive agents. The composition of Hughes may also contain surfactants (column 6, lines 34-48), soluble fluoride ions such as sodium fluoride, stannous fluoride (column 6, lines 49-55), anti-calculus agents, of which specific example is zinc compounds (column 6, line 59 to column 7 line 22), sweetening and flavoring agents at 0.005 to about 2% and humectants (column 7, lines 23-26, 43), bleaching agent (column 7, line 52 to column 8, line 45), optional agents such as dyes/colorant, pH adjusting agents, plant extracts and desensitizing agents such as potassium nitrate, and mixtures thereof (column 7, lines 27-41), and effervescent agents such as carbonate that are effective under acidic conditions and mixed with organic acids such as citric acid, malic acid, succinic acid and gluconic acid (column 8, lines 13-23). The composition may also contain polyethylene glycols (column 10, lines 60 and 61) and phosphonic acid chelating agents

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at 0.1-1% (column 12, line 16); and the composition contains from about 0-60% or 5-30% ethanol when it is a mouthwash (column 7, line 45) meeting claims 20 and 42. The xanthan gum and polyethylene glycol meet the limitation of polymer in claims 1, 12 and 36 and 44-46. The presence of phosphonic acid, citric acid meets the acid requirements of claims 1, 11 and 35, 44-46. The fluoride ions meet the requirements of claims 14 and 37; potassium nitrate is a source of potassium ion meeting claims 15 and 38; carboxymethylcellulose meets the film-forming agent of claim 1; the sweetening agent at 0.005 to about 2% meets claims 19 and 41. Applying the composition containing desensitizing agent meets claim 27 and the composition of Hughes meets claims 18 and 40. The solubility of the acid recited in claims 2 and 33 is a property of the acid so that the acid of Hughes, which is the same phosphonic acid as in the claims, would have those properties and thus meet claims 2 and 33. Regarding claims 17 and 39, one film-forming agent may replace another without negatively affecting the composition. In this case, hydroxypropyl cellulose could be substituted for carboxymethyl cellulose with the expectation that the composition would be effective as a dentifrice.

7. Hughes discloses the claimed composition as described above. The difference between the Hughes composition and the claimed composition is that while Hughes teaches that the composition can be acidic, Hughes does not specifically teach a pH of from 2 to 3. However, Asano describes dentifrice composition containing fluoride ion from potassium or sodium fluoride at 0.0025 to 4%, zinc ions, polyethylene glycol, hydroxyl ethyl cellulose, silica abrasive, xanthan gum or carrageenan at 0.2 to 5%, humectants, succinic acid or gluconic acid or maleic acid or fumaric acid as buffering agents; 0.01 to 2% flavoring agent/sweetening; ethanol/water solvent; Asano specifically teaches that the pH of the composition should be maintained at acidic

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pH of 3.5 to 6 in order to permit the fluoride to remain in solution instead of precipitating (abstract; column 2, line 39- 55; column 3, lines 7-59, column 4, lines 2, 11-14, 17-37; column 5, lines 30-43; Example 8 and claims 1-11). The pH for the composition of claim 43 is the same as that of the generic claims 1 and 44-46 so that once the pH of the composition in 1 is rendered obvious then the pH of claim 43 would also be rendered obvious.

8. Hughes contemplates using the composition at acidic pH. Asano specifically teaches that pH of 3.5 to 6 is suggested dentifrice composition to permit the fluoride to remain in solution. Thus, pHs of dentifrices or mouth washes are result effective parameters. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the pH of the composition of Hughes according to the teachings of Asano to maintain the pH at acidic pHs of 3.5 to 6 or lower in order to maintain the fluoride in solution. Thus, when Hughes in view of Asano are taken together, the ordinary skilled artisan would have been motivated to maintain the pH of the composition at acidic pH in order that the fluoride can be maintained in solution as a low pH is expected to maintain the fluoride and zinc ions in solution.

Response to Arguments

9. Applicant's arguments filed 01/12/2011 have been fully considered but they are not persuasive.

10.

11. Applicant argues that the claimed invention is a liquid composition for desensitizing teeth having a pH of from 2 to 3 and that none of the cited references teach the composition as claimed.

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12. Response: The examiner agrees with applicant that none of the references teach the composition of the claims having a pH of from 2-3 and that is why a rejection under 35 USC 103 is made. Desensitization of teeth by a composition is the intended use characteristic of that composition. The suggestion by the prior art that the pH of the solution should be kept at acidic pH to keep the fluoride in solution is a persuasive suggestion to keep the pH acidic and the pH is a motivation to determine the pH where within the disclosed pH range of 3.5-6 would be optimum to produce the desired mouthwash composition in which the fluoride is in solution. A pH of 3 and 3.5 are both acidic and using acidic pH for the disclosed liquid composition is an optimization of the composition.

13. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In *re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382, it was disclosed that “The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.”

14. Therefore, guided by *Hughes* and *Asano*, the artisan would be motivated to keep the liquid composition acidic. “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In *re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

15. The burden shifted to applicant to show that a pH of 3 or 2 provides unexpected results over acidic pH such as 3.5. No factual showing has been presented to show that a pH of 3 provides unexpected results over a composition having a pH of 3.5 say. Since the solubility of

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fluoride is dependent on acidic pH, it flows that the pH is results effective and the pH would thus be optimized to provide optimum composition in which the fluoride is soluble.

16. Therefore, claims 1, 2, 11, 12, 14, 15, 17-20, 27, 33 and 35-46 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes et al. (US 6,004,538) in view of Asano et al. (US 4,568,540).

17. No claim is allowed.

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

19. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **BLESSING FUBARA** whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

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21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Y. Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1613